
ACTIVE PHARMACEUTICAL INGREDIENTS COMMITTEE

A SECTOR GROUP OF  CEPIC

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
USA

Docket No. 99N-1415

8 November 1999

Dear Sirs,

Please find hereunder the comments from:

CEPIC/APIIC (European Chemical Industry
Council/Active Pharmaceutical Ingredients Committee)
Avenue E. van Nieuwenhuyse 4, bte 2
B-1160, Brussels
Belgium
Contact person: Mr. Loïc Le Doré
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on FDA's Proposed Rule on "Supplements and Other Changes to Approved New Animal Drug Applications" (23 June 1999), issued for comments in the Federal Register on 1 October 1999.

CEPIC is the organization representing national federations, companies and more than 100 affiliated associations and sector groups, located in Europe. All together CEPIC represents directly or indirectly more than 40,000 large, medium and small chemical companies in Europe, which employ about 2 million people and account for more than 30% of the world's chemical production.

APIIC is one of CEPIC's sector groups, comprising producers of active pharmaceutical ingredients (APIs) and intermediates in Europe. The major part of the total volume of APIs and intermediates imported into the USA originates from Europe. For this reason, CEPIC/APIIC considers itself to be a very important stakeholder in new FDA Regulations and Guidances related to APIs and intermediates.

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We, therefore, highly appreciate this opportunity for submitting our European APIs- and intermediates manufacturing members' comments on the above mentioned Proposed Rule, which in part deals with changes relating to the manufacture of our products.

Because our comments on this new Draft Proposed Rule are exactly identical to the ones we have submitted recently on the Draft Proposed Rule "Supplements and Other Changes to an Approved Application" (18 June 1999), we request that FDA will consider our previously submitted comments as also applying to this new Veterinary Proposed Rule.

A copy of our previous comments is enclosed as well as a copy of our comments submitted simultaneously to the new Draft Guidance "Chemistry, Manufacturing and Controls Changes to an Approved NADA or NADA".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Loïc Le Doré', with a stylized, cursive script.

Loïc Le Doré
Secretary General
CEFIC/APIIC

- Enclosures

AIRMAIL

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P.O. Box 101 / 21
1934 Brussel X-Airport

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(HFA - 305)

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